



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0215]

Agency Information Collection Activities; Proposed Collection; Comment Request; Health Care Professional Survey of Professional Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Health Care Professional Survey of Professional Prescription Drug Promotion.” This study will examine how health care professionals experience and perceive prescription drug promotion directed to them.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments

until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2018-N-0215 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Health Care Professional Survey of Professional Prescription Drug Promotion.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made

publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register*

concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Health Care Professional Survey of Professional Prescription Drug Promotion

OMB Control Number 0910--NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

As part of its federal mandate, FDA regulates whether direct-to-consumer (DTC) advertising of prescription drug products is truthful, balanced, and accurately communicated (see 21 U.S.C. 352(n)). Similarly, the FD&C Act prohibits the dissemination of false or misleading information about medications in consumer-directed and professional prescription drug

promotion. FDA regulates within the framework of free speech and due process principles of the United States Constitution. To inform current and future policies, and to seek to enhance audience comprehension, the Office of Prescription Drug Promotion conducts research focusing on (1) advertising features including content and format, (2) target populations, and (3) research quality. This proposed research focuses on the physician target population. FDA surveyed physicians about their attitudes toward DTC advertising and its role in their relationships with their patients in 2002 (Ref. 1) and again in 2013 (Refs. 2 and 3). The 2013 survey included multiple types of prescribers: primary care physicians, specialists, nurse practitioners, and physician assistants. Whereas the focus of both previous FDA surveys was on DTC advertising and promotion, the current study is designed to address issues related to professional prescription drug promotion. The goal is to query a representative sample of health care professionals (HCPs) about their opinions of promotional materials and procedures targeted at HCPs, clinical trial design and knowledge, and FDA approval status. We will also take this opportunity to ask HCPs briefly about their knowledge of abuse-deterrent formulations for opioid products.

To educate themselves about prescription drugs, HCPs sometimes rely on professionally directed promotional information (Refs. 4-8). In 2012, pharmaceutical companies spent more than \$24 billion on marketing to physicians (Ref. 9). The industry exposes health care professionals to promotional materials through a variety of mechanisms, including communication with pharmaceutical representatives, journal ads, prescribing software, presentations at sponsored meetings, and direct mail ads (Ref. 10). Several studies indicate that data presented in promotional materials may not be fully comprehended and may even potentially be misleading due to a variety of causes, such as insufficient information,

unsupported claims, or a failure to disclose limitations of the information presented (Refs. 11-15).

Although HCPs are learned intermediaries, like most people, they may rely on heuristics in making decisions and may have cognitive biases in the type of information they attend to at any given time. They may be persuaded by strong statements and may not have the time to ascertain accuracy of such information (Ref. 16). The proposed survey will provide further insights about how professionally targeted prescription drug promotion might influence health care professionals' decision-making processes and practices and how information may be communicated more effectively. It is important to note that FDA does not regulate the practice of medicine. However, as previously mentioned, FDA does regulate prescription drug promotion. This survey is designed to inform FDA of various responses to and impacts of prescription drug promotion of prescription drugs.

The general research questions in the survey are as follows:

1. What methods and/or channels are used to disseminate prescription drug promotional information to health care professionals/prescribers?
2. How knowledgeable and interested are HCPs in clinical trial data and its presence in prescription drug promotion?
3. How familiar are HCPs with the FDA approval of prescription drugs and how does this translate into practice?

In addition, given the critical nature of the opioid situation in the United States at this time, we plan to ask several questions about prescription drug promotion of opioid products.

HCPs who fall into one of four categories will be recruited online through WebMD's Medscape subscriber network. We propose to complete 700 primary care physician, 600

specialist, 350 nurse practitioner, and 350 physician assistant surveys. HCPs will be included if they see patients at least 50 percent of the time. Both Doctors of Medicine and Doctors of Osteopathy will be included. Primary care physicians will include those who indicate they work in general, family, or internal medicine. Specialties were chosen based on prevalence in the United States and prescription drug promotional activity. Specialists will include cardiologists, dermatologists, endocrinologists, neurologists, obstetrician/gynecologists, oncologists, ophthalmologists, psychiatrists, rheumatologists, and urologists. The data will be weighted to adjust for differential coverage of select characteristics such as region and respondent age and gender. Pretesting with 25 respondents will take place before the main study to evaluate the procedures and measures used in the main study.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pretest Study					
HCP screener	63	1	63	0.08 (5 minutes)	5
Informed Consent	25	1	25	0.08 (5 minutes)	2
HCP Survey	25	1	25	0.33 (20 minutes)	8
Main Study					
HCP screener	5,037	1	5,037	0.08 (5 minutes)	403
Informed Consent	2,000	1	2,000	0.08 (5 minutes)	160
HCP Survey	2,000	1	2,000	0.33 (20 minutes)	660
Total					1,238

<sup>1</sup>There are no capital costs and maintenance costs associated with this collection of information.

## II. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m.,



Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Available at:

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm>. Last accessed January 26, 2018.

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3. O'Donoghue, A.C., V. Boudewyns, K.J. Aikin, et al. (2015). "Awareness of FDA's Bad Ad Program and Education Regarding Pharmaceutical Advertising: A National Survey of Prescribers in Ambulatory Care Settings," *Journal of Health Communication*, vol. 20(11), pp. 1330-1336.

4. Crigger, N.J. (2005). "Pharmaceutical Promotions and Conflict of Interest in Nurse Practitioner's Decision Making: The Undiscovered Country," *Journal of the American Academy of Nurse Practitioners*, vol. 17(6), pp. 207-212.

5. Fischer, M.A., M.E. Keough, J.L. Baril, et al. (2009). "Prescribers and Pharmaceutical Representatives: Why Are We Still Meeting?" *Journal of General Internal Medicine*, vol. 24(7), pp. 795-801.

6. C. Robertson, S. Rose, and A.S. Kesselheim. (2012). "Effect of Financial Relationships on the Behaviors of Health Care Professionals: A Review of the Evidence," *The Journal of Law, Medicine & Ethics*, vol. 40(3), pp. 452-466.

7. Srivastava, V., M. Handa, and A. Vohra. (2014). "Promotional Tools: Do Physicians Really Bite the Hook?" *Drishtikon: A Management Journal*, vol. 5(2).
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12. Cooper, R.J. and D.L. Schriger. (2005). "The Availability of References and the Sponsorship of Original Research Cited in Pharmaceutical Advertisements," *Canadian Medical Association Journal*, vol. 172(4), pp. 487-491.
13. Jureidini, J.N., L.B. McHenry, and P.R. Mansfield. (2008). "Clinical Trials and Drug Promotion: Selective Reporting of Study 329," *International Journal of Risk & Safety in Medicine*, vol. 20(1-2), pp. 73-81.
14. Garcia-Retamero, R. and M. Galesic. (2010). "Who Profits From Visual Aids: Overcoming Challenges in People's Understanding of Risks," *Social Science & Medicine*, vol. 70(7), pp. 1019-1025.

15. Cooper, R.J., D.L. Schriger, R.C. Wallace, et al. (2003). “The Quantity and Quality of Scientific Graphs in Pharmaceutical Advertisements,” *Journal of General Internal Medicine*, vol. 18(4), pp. 294-297.

16. Sah, S. and A. Fugh-Berman. (2013). “Physicians Under the Influence: Social Psychology and Industry Marketing Strategies,” *The Journal of Law, Medicine & Ethics*, vol. 41(3), pp. 665-672. doi: 10.1111/jlme.12076.

Dated: March 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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